MIS Implants Technologies Ltd.

K103089

510(k) Summary:

SEP 15 2011

MIS Short Implants

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Establishment Registration Number: 3004203816

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Date prepared: August 21st, 2011

Trade Name: MIS Short Implants

Classification name: Implants, Endosseous, Root Form

Common/usual name: Dental Implant

Product Code: DZE

Regulation No.: 872.3640

Class: II

Panel identification: Dental Devices Panel

Predicate Device:

4.5x6.0mm and 6.0x6.0mm dental implants cleared under 510(k) K050712 and 5.0x6.0mm cleared under 510(k) K042637, both from Bicon, Inc. 501Arborway, Boston, Massachusetts, 02130;

OsseoSpeed 4.0S – 6 mm implant cleared under 510(k) K063779 from Astra Tech Inc., 890 Winter Street, Suite 310, Waltham, MA 02451.

Description of the device:

The MIS short implants are self tapping, root-form, two piece screw type dental implants, indicated for use in surgical and restorative applications for placement in the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function.

The MIS short implants are provided in 6.0mm length and 4.2mm, 5.0 mm, and 6.0mm diameters, as follows:

Seven internal hexagon 6.0mm length: diameter 4.20mm, 5.0 mm and 6.0mm

Biocom internal hexagon 6.0mm length: diameter 4.20mm, 5.0 mm and 6.0mm

Lance internal hexagon 6.0mm length: diameter 4.20mm, 5.0 mm and 6.0mm

The implants surface is sand blasted and acid etched.

The MIS short implants are two piece devices whereas the implant is to be used in combination with cover screws, healing caps, abutments and superstructures.

The MIS short implants are made of Ti6AL4V ELI complying with standard ASTM F 136-08- Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.

Indications for Use:

MIS dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.

MIS short implants are to be used only with straight abutments.

Substantial Equivalence:

The MIS short implants have the same intended use as the 4.5x6.0mm and 6.0x6.0mm cleared under 510(k) K050712 and 5.0x6.0mm dental implants cleared under 510(k) K042637, both from Bicon, Inc. 501 Arborway, Boston, Massachusetts, 02130, and the OsseoSpeed 4.0S – 6 mm implant cleared under 510(k) K063779 from Astra Tech Inc., 890 Winter Street, Suite 310, Waltham, MA 02451, and have equivalent performance characteristics. All these products are manufactured from the same Titanium alloy. All other technological characteristics are similar and show equivalent performance capabilities. The MIS short implants are therefore substantially equivalent to their predicate devices.

Technological characteristics – comparative table:

	MIS Short Implants from MIS Implants Technologies Ltd.	**4.5x6.0mm 6.0x6.0mm Implants from Bicon, Inc.**	**5.0x6.0 mm Implant from Bicon, Inc.**	**OsseoSpeed from Astra Tech Inc.**
Indications For Use	MIS dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is	The 4.5x6.0 mm and the 6.0mmx6.0mm implants are designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridgework, partial dentures, or a single tooth replacement.	The 5.0x6.0 mm implant is intended to be surgically placed in the maxilla or mandible to provide support for prosthetic devices to restore the patient's chewing function.	The OsseoSpeed™ 4.0S – 6 mm is intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla where immediate implant stability may be obtained. The device may be used equally well in a single-stage or two-stage surgical procedure. It is indicated for immediate implantation in extraction sited or implantation in partially healed or completely healed alveolar ridge situations. When a one-stage surgical approach is applied, the implant may be immediately loaded after implantation where immediate implant stability

	MIS Short Implants from MIS Implants Technologies Ltd.	4.5x6.0mm 6.0x6.0mm Implants from Bicon, Inc.	5.0x6.0 mm Implant from Bicon, Inc.	OsseoSpeed from Astra Tech Inc.
	appropriate. MIS short implants are to be used only with straight abutments.			may be obtained. The fluoride-modified surface, though having a fluoride ion level far below that needed for caries prevention in teeth, provides a favorable substrate for bone attachment and osseointegration. OsseoSpeed 4.0S – 6 mm is especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective. Because initial stability may be difficult to obtain in Type IV bone, immediate loading of single tooth restorations may not be appropriate in such situations.
Supplied Sterile	Yes	Yes	Yes	Yes
Re-use	No	No	No	No
Material of Construction	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Shape	Screw type	Screw type	Screw type	Screw type
Length	6.0 mm	6.0 mm	6.0 mm	6.0 mm
Thread Diameter	4.2, 5.0 and 6.0 mm	4.5 and 6.0 mm	5.0 mm	4.0
Abutment	Straight	Straight and up to 25°	Straight and up to 25°	Straight and up to 20°
Material of Construction of Abutments	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Surface Treatment of Abutments	None	None	None	None

Non – clinical tests:

Fatigue test was performed on MIS short implants and its results were found equivalent to those of their predicate devices.

Clinical tests:

A clinical evaluation, based on literature review and case studies with 30 months follow up, has been performed.

Conclusion:

The evaluation of the MIS short implants does not raise any additional concerns regarding safety and effectiveness and the MIS short implants may therefore be considered substantially equivalent to their predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Iman Khorshid
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MIS Implants Technologies, Limited
P.O. Box 7 Bar Lev Industrial Park
20156, ISRAEL

SEP 15 2011

Re: K103089
Trade/Device Name: MIS Short Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 11, 2011
Received: September 13, 2011

Dear Ms. Khorshid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MIS Implants Technologies Ltd.

INDICATIONS FOR USE

510(k) Number: K103089

Device Name: MIS Short Implants

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MIS short implants are to be used only with straight abutments.

Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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